Process for Adding Duke Medical and Graduate Students to Study Personnel

1. Graduate students may be added as key personnel to research protocols without additional approvals, however the IRB and CRU may impose restrictions on the specific roles of graduate students in research.
2. Graduate students are limited to conducting supervised clinical research activities that would normally be permitted as part of their clinical training.
3. All graduate students on research teams must be adults (18 yrs. or older).
4. All graduate students must complete the same CITI modules as all other Duke researchers. Click here for the CITI web site. Be sure to affiliate with ?Duke Health? on the CITI web site.
5. A personnel change adding the graduate student to key personnel must be submitted in iRIS. The individual?s role should be indicated as ?Graduate Student.?

Process for Adding Duke Undergraduate Students to Study Personnel

1. All Duke undergraduates on research teams must be adults (18 yrs. or older). The process below should be followed for Duke undergraduates who are unpaid volunteers, regardless of whether they are receiving academic credit. Duke undergraduates who are hired as research personnel and are Duke employees may be added as key personnel after meeting the standard requirements for key personnel, however, should their employment status change, they must be updated in iRIS.
2. All Duke undergraduates must complete the same CITI modules as all other Duke Health researchers. Click here for the CITI web site. Be sure to affiliate with ?Duke Health? on the CITI web site. Please upload the CITI completion report, documenting completion of required modules, in the eIRB.
3. One of two agreement letters must be completed by the study team and signed by the Duke undergraduate and the Office of Research Contracts. The volunteer agreement letter is intended for unpaid interns or volunteers, including Duke undergraduate students, who are NOT engaged in conducting the consent process. The agreement letter for Duke undergraduates engaged in the consent process is intended for only unpaid, undergraduate Duke students engaged in the consent process.
4. An email must be sent to your CRU medical director or Oversight Organization director
(or Dept. Chair if you are not part of a CRU) containing the following:

- Name of Duke undergraduate
- Pro# of study
- PI
- Specific description of the individual’s role on the study (including whether the individual will be conducting the consent process (Duke undergraduate students only)) and expected time on study team
- Please ask the CRU medical director or Oversight Organization director (or designee) to respond with an approval via email.

5. A regular amendment must be submitted in iRIS to add the Duke undergraduate to external key personnel for each study on which he/she participates. The amendment must contain copies of:

- The appropriate signed volunteer agreement letter
- Approval (email) from CRU Medical Director or Oversight Organization Director
- CITI module completion report
- If appropriate, the Undergraduate Student Informed consent workshop completion report.

Once the IRB has approved the regular amendment, the Duke undergraduate may join the study team.

6. Duke undergraduates may not have access under any circumstances to a subject’s or patient’s electronic medical record.

7. All work by the Duke undergraduate must be conducted on-site under the supervision of the PI or other designated study team members. In addition, all work by the Duke undergraduate must be conducted on Duke computers and servers. Remote access to Duke servers will not be permitted. Use of personal electronics by the Duke undergraduate for storage/analysis/receipt of information involving Duke research studies is not permitted.

8. Additionally, please refer to the Duke HR (Human Resources) web site, Volunteer & Unpaid Intern Policy Guidelines.

Process for Adding Other Unpaid Volunteers, Visiting Students, and Visiting Scholars to Study Personnel

1. Interns and volunteers on research teams must be adults (18 yrs. or older).

2. All unpaid interns/volunteers must complete the same CITI modules as all other Duke Health researchers. Click here for the CITI web site. Be sure to affiliate with ?Duke Health? on the CITI web site. Please upload the CITI completion report, documenting completion of required modules, in iRIS.

3. A clean criminal background check must be obtained on each unpaid intern/volunteer.

- Please contact:
4. The volunteer agreement letter or applicable visiting scholar letter signed by the Office of Research Contracts (ORC) must be completed. Please contact Susan Hayden, JD from ORC for these letters. Her email is susan.hayden@duke.edu

5. An email must be sent to your CRU medical director or Oversight Organization director (or Dept. Chair if you are not part of a CRU) containing the following:

- Unpaid Intern/Volunteer Name
- Pro# of study
- PI
- Specific description of the individual’s role on the study (including whether the individual will be conducting the consent process (Duke undergraduate students only)) and expected time on study team
- Please ask the CRU medical director or Oversight Organization director (or designee) to respond with an approval via email.

6. A regular amendment must be submitted in iRIS to add the unpaid intern/volunteer to external key personnel for each study on which he/she participates. The amendment must contain copies of:

- The appropriate signed volunteer or visiting scholar agreement letter
- Approval (email) from CRU Medical Director or Oversight Organization Director
- CITI module completion report
- Statement from the PI that a clean criminal background check has been obtained for non-Duke student volunteers (do not upload the actual criminal background report itself)

Once the IRB has approved the regular amendment, the unpaid intern/volunteer may join the study team.

7. Unpaid interns/volunteers may not have access under any circumstances to a subject’s or patient’s electronic medical record.

8. Unpaid interns/volunteers may be granted Duke email accounts and access to shared drives specified by the PI. However, all work by the unpaid intern/volunteer must be conducted on-site under the supervision of the PI or other designated study team members. In addition, all work by the unpaid intern/volunteer must be conducted on Duke computers and servers. Remote access to Duke servers will not be permitted. Use of personal electronics by the unpaid intern/volunteer for storage/analysis/receipt of information involving Duke research studies is not permitted.